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BEFORE THE BOARD OF APPEALS AND INTERFERENCES
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Serial No. 09/758,003

Applicant: Vijay R. Baichwal

Filed: Jan 09, 2001

Docket No. T95-006-2

Title: *RIP: Novel Human Protein Involved in Tumor Necrosis Factor Signal Transduction*

Customer No. 23379

Confirmation No. 8531

Group Art Unit: 1646

Examiner: Andres, Janet L.

CERTIFICATE OF MAILING
I hereby certify that this corr. is being deposited with the US Postal Service as First Class Mail in an envelope addressed to the Comm. for Patents, PO Box 1450, Alexandria, VA 22313-1450 on October 9, 2004.

Signed _____
Richard Osman

REPLY BRIEF ON APPEAL

The Honorable Board of Appeals and Interferences
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Honorable Board:

This Reply Brief is responsive to the Examiner's Answer dated Aug 11, 2004.

Our Brief on appeal properly groups our claims and, in our argument, we provided basis for each recited grouping. The Answer's disagreement with our grouping of the claims is improper, and appears to reflect a misapprehension of the purpose of our discretionary grouping of the claims.

I. THE EXAMINER'S REJECTION OF CLAIMS 1, 3, 5, 6, 10-27 and 29-34 UNDER 35USC112, FIRST PARAGRAPH (WRITTEN DESCRIPTION) IS IMPROPER.

The subject matter of claims 1, 3, 5-6, 10-27 and 29-34 is described in the Specification pursuant to 35USC112, first paragraph, and we are unable to discern in the Final Action any supported, contrary allegation. The Specification discloses a novel RIP variant, having Thr at position 514. The Specification describes, and the pending claims are all properly restricted to probes (or reagents or making probes) which distinguish the novel RIP variant (and its corresponding cDNA) from RIP-Ser^{514}.

Claims 1, 5 and 6 (and all dependencies of claim 1) all require that the polynucleotide encode a RIP-Thr^{514} polypeptide comprising at least 10 consecutive amino acid residues of SEQ ID NO:2, which consecutive residues include residue 514 (Thr). Hence, the required region of the encoded polypeptide is not "only one amino acid", but one of the only ten possible decapeptides of SEQ ID NO:2 that includes residue 514 (Thr). In addition, the encoded polypeptide is functionally limited to those immunologically distinguishable from RIP-Ser^{514}. The Specification describes and exemplifies these recited polynucleotides (e.g. p.3, lines 13-31).

Claim 3 and its dependencies are all structurally limited to a RIP-ACA$^{1540-1542}$ nucleic acid comprising at least 24 consecutive nucleotides of the nucleotide sequence set forth as SEQ ID NO:1, which consecutive nucleotides comprise nucleotides 1540-1542 (ACA) of SEQ ID NO:1. Hence, the required common region is limited to one of the only 22 possible 24-mers that include 1540-1542 (ACA) of SEQ ID NO:1. In addition, the nucleic acid is functionally limited to those which hybridize with RIP-ACA$^{1540-1542}$ cDNA but not with RIP-TCT$^{1540-1542}$ cDNA. The Specification describes and exemplifies these recited polynucleotides (e.g. p.4, lines 1-24).

Claims 10-27 are further limited to polynucleotides encoding a RIP-Thr^{514} polypeptide comprising a particularly disclosed RIP-Thr^{514} truncation meeting the limitations of claim 1 (i.e. wherein the polypeptide comprises at least 10 consecutive residues of SEQ ID NO:2 which comprise the amino acid residue 514 (Thr), wherein the polypeptide is immunologically distinguishable from RIP-Ser^{514}). These particular truncations are all specifically described (Specification, p.3, lines 22-31); and hence further remove these claims from the Action's written description rejection.

Claims 29-34 are further limited to polynucleotides comprising a RIP-ACA$^{1540-1542}$ nucleic acid comprising a particularly disclosed RIP-ACA$^{1540-1542}$ polynucleotide meeting the limitations of claim 3 (i.e. wherein the polynucleotide comprises at least 24 consecutive nucleotides of SEQ ID NO:1 which comprise nucleotides 1540-1542 (ACA)). These particular polynucleotides are all specifically described (Specification, p.4, lines 8-24); and hence further remove these claims from the Action's written description rejection.

Our Specification plainly provides a written description that reasonably conveys to one skilled in the art that the inventors at the time the application was filed, had possession of the claimed invention, and we maintain that the Office Actions cited by the Answer provide no supported, contrary allegation. The Answer complains that "there is no upper size limit and no limit as to the nature of the sequence other than that they contain the required fragment."

Answer, p.7, lines 11-13. Firstly, this complaint is falsely premised: all our claims impose a functional limitation on the recited polypeptide or polynucleotide. And secondly, this complaint is applicable to any claim using the open transition, "comprising". Of course a would-be infringer can not misappropriate our invention by merely adding some arbitrary additional sequence to our disclosed polynucleotides. The law does not require us to impose an arbitrary upper size limit to the claimed polynucleotide, inviting the unscrupulous infringer to take that number, add an arbitrary nucleotide, and walk off with our invention. Our Specification clearly describes how the recited sequences may be joined to a wide variety of additional sequences. Specification, p.3, line 5; p.5, lines 13-15, etc. Even the exemplary polypeptide and polynucleotide sequences of Tables 1 and 2 (Specification, p.3, lines 22-31 and p.4, lines 11-24) *comprise* sequences in addition to the required sequences. Just as with the "comprising" claims found allowable by the Examiner in this application, our claims are properly open to additional sequences, and properly impose no arbitrary upper size limit, nor an arbitrary limit as to the nature of such additional sequences.

II. THE EXAMINER'S REJECTION OF CLAIMS 1, 3, 5, 6, 10-27 and 29-34 UNDER 35USC112, FIRST PARAGRAPH (ENABLEMENT) IS IMPROPER.

Claims 1, 3, 5-6, 10-27 and 29-34 are drawn to properly, separately disclosed polynucleotides. That the Sequence Listing rules permit us to describe these separately disclosed molecules with reference to a single inclusive SEQ ID NO does not mean that we disclose only a single molecule comprising that inclusive SEQ ID NO.

An enablement rejection requires a showing that one skilled in the art could not practice the invention as claimed without undue experimentation. In their broadest recitations, the claims require use of either (a) a polynucleotide encoding a RIP-Thr^{514} polypeptide comprising at least 10 consecutive amino acids of SEQ ID NO:2 which comprise the amino acid residue 514 (Thr) of SEQ ID NO:2, wherein the polypeptide is immunologically distinguishable from RIP-Ser^{514}; or (b) a RIP-ACA$^{1540\text{-}1542}$ nucleic acid comprising at least 24 consecutive nucleotides of SEQ ID NO:1 which comprise nucleotides 1540-1542 (ACA) of SEQ ID NO:1, wherein the nucleic acid hybridizes with RIP-ACA$^{1540\text{-}1542}$ cDNA but not with RIP-TCT$^{1540\text{-}1542}$ cDNA.

As noted above, with regards to Claim 1, 5 and 6 (and all dependencies of claim 1), there only ten possible decapeptides of SEQ ID NO:2 that includes residue 514 (Thr). In addition, the encoded polypeptide is functionally limited to those immunologically distinguishable from RIP-

Ser^{514}. The Specification describes and exemplifies these recited polynucleotides (e.g. p.3, lines 13-31). Similarly, with regards to claim 3 and its dependencies, there are only 22 possible 24-mers that include 1540-1542 (ACA) of SEQ ID NO:1. In addition, the nucleic acid is functionally limited to those which hybridize with RIP-$ACA^{1540-1542}$ cDNA but not with RIP-$TCT^{1540-1542}$ cDNA. The Specification describes and exemplifies these recited polynucleotides (e.g. p.4, lines 1-24).

Ascertaining whether a given polynucleotide falls within the claim requires no more than determining if one of the ten (or 22 in the case of claim 3) possible sequences are present, and using routine screening to determine if the requisite binding/hybridization function is met.

Note that the claims do not encompass any inoperable embodiments; though the claims would be compliant with the enablement requirement even if there were inoperable embodiments. Furthermore, ascertaining the suitability of any given candidate peptide species is well within the bounds of empirical experimentation permitted by the enablement requirement of 35USC112, as defined by applicable Federal Circuit law; see *In re Wands* (8 USPQ2d 1400 (Fed Cir 1988).

The empirical experimentation necessary to practice alternative embodiments of our invention is less than that permitted under *Wands*. Substituting and testing alternative sequences in the Specification-taught simple binding or hybridization assays does not approach the experimentation required by Wands. Our Specification provides more than sufficient teaching to enable one of ordinary skill in this art to practice the claimed invention without undue experimentation. As the 35USC112-compliant experimentation required to generate and screen monoclonal antibodies per *Wands* in 1980 is more extensive and unpredictable than that required here, our claims are in compliance with the enablement requirement of 35USC112.

The rejection appears premised on our claims' use of the open transition "comprising"; like any "comprising" claim, our claims do not preclude additional elements, such as additional nucleotides, beyond those recited – just as do our claims 28 and 35, deemed allowable by the Examiner.

Claims 10-27 are further limited to polynucleotides encoding a RIP-Thr^{514} polypeptide comprising a particularly disclosed RIP-Thr^{514} truncation meeting the limitations of claim 1 (i.e. wherein the polypeptide comprises at least 10 consecutive residues of SEQ ID NO:2 which comprise the amino acid residue 514 (Thr), wherein the polypeptide is immunologically distinguishable from RIP-Ser^{514}). These particular truncations are all specifically exemplified

(Specification, p.3, lines 22-31); and hence further remove these claims from the Action's enablement rejection.

Claims 29-34 are further limited to polynucleotides comprising a RIP-ACA$^{1540\text{-}1542}$ nucleic acid comprising a particularly disclosed RIP-ACA$^{1540\text{-}1542}$ polynucleotide meeting the limitations of claim 3 (i.e. wherein the polynucleotide comprises at least 24 consecutive nucleotides of SEQ ID NO:1 which comprise nucleotides 1540-1542 (ACA)). These particular polynucleotides are all specifically exemplified (Specification, p.4, lines 9-24); and hence further remove these claims from the Action's enablement rejection.

Our Specification plainly enables one skilled in the art to practice the invention, and we maintain the Answer provides no supported, contrary allegation. The law does not require us to impose an arbitrary upper size limit to the claimed polynucleotide (see, e.g. Answer, p.10, line 17), inviting the unscrupulous infringer to take that number, add an arbitrary nucleotide, and walk off with our invention. Our Specification clearly describes how the recited sequences may be joined to a wide variety of additional sequences. Specification, p.3, line 5; p.5, lines 13-15, etc. Even the exemplary polypeptides and polynucleotides of Tables 1 and 2 (Specification, p.3, lines 22-31 and p.4, lines 11-24) *comprise* further sequences in addition to the required sequence. Just as with the "comprising" claims found allowable by the Examiner in this application, our claims are properly open to additional sequences, and properly impose no arbitrary upper size limit, nor an arbitrary limit as to the nature of such additional sequences.

The practitioner uses polynucleotides "comprising" the recited sequences exactly as taught, in expression vectors, templates for transcription, hybridization probes, PCR primers, binding assays, etc. (e.g. Specification, p.3, lines 5-12; p.3, lines 19-20; p.4, lines 4-7; and Examples 3 and 4).

The Answer offers a novel test for enablement, wherein one skilled in the art is required to test every molecule that could "potentially" be within the scope of the claims (Answer, p.11, line 16). Depending on what she means by "potentially", this test could indeed flunk just about every claim every granted by the USPTO.

Finally, unable to distinguish *In re Wands*, 8 USPQ2d 1400 (Fed Cir 1988), the Answer resorts to a rhetorical slight of hand. She leads in with an accurate statement: "... in *Wands*, one of skill in the art could, and would routinely expect to produce an antibody meeting the limitations of the claims." Answer, p.11, line 21 - p.12, line 1. But then carefully note her subsequent false contrast: "However, the instant claims require not just one successful outcome

of an experiment, as is described in *Wands*. They encompass an entire genus of molecules...." Answer, p.12, lines 1-3.

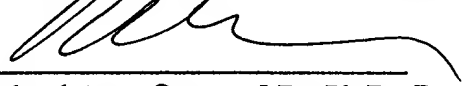
What logically *should* follow the Answer's phrase "the instant claims require *not just one* successful outcome of an experiment" is, of course, that "they require *more than one* successful outcome of an experiment". But of course, the Answer can not make that argument, because our claims do not require any experimental outcomes – the practitioner may practice the invention with the exemplified sequences.

Instead, the Answer follows that phrase incongruously: "the instant claims require not just one successful outcome of an experiment ... they encompass an entire genus of molecules." Why the incongruous argument? Of course, the Answer could have congruously argued: "the instant claims encompass not just one molecule... they encompass an entire genus of molecules." But that statement is innocuous, and applies equally to Wands' claims.

The Answer's argument is logically incongruous because a congruous argument does not support the rejection. Th claims in Wands also encompassed an entire genus of molecules. The issue in *Wands* was not whether making every possible monoclonal antibody encompassed by the claims required undue experimentation (a practically impossible task), but rather whether making such an antibody required such experimentation. Here, making and using our properly claimed polynucleotides is a far less taxing endeavor than making and using the monoclonal antibodies properly claimed by Wands.

Appellants respectfully request reversal of the pending Final Action by the Board of Appeals.

Respectfully submitted,
SCIENCE & TECHNOLOGY LAW GROUP



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